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10/749,877	12/31/2003	David Z.J. Chu	54435.8002.US01	6326
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PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			ART UNIT 3732	PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

10/749,877

Applicant(s)

CHU, DAVID Z.J.

Examiner

Cary E. O'Connor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28, 31-41 and 44-69 is/are rejected.
- 7) ☒ Claim(s) 29, 30, 42 and 43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4-22-04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 31, 49-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites the limitation "the...central rod and/or the end receptacle" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 31 recites the limitation "the central rod" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 49 recites the limitation "the plurality of openings" in lines 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 50 recites the limitation "the anchoring plates" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 52 recites the limitation "the anchoring plates" in line 2. There is insufficient antecedent basis for this limitation in the claim.

As to claim 63, the phrase "retractor is be removably" is unclear.

As to claim 64, line 3 is unclear in that it is not understood how and opening can have apertures. Furthermore, the claim ends with "and".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 9, 11, 13, 49-52, 54, 55, 59, 61 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Klingenstein (5,730,726). As to claim 9, Klingenstein shows an expandable surgical retractor comprising a central rod 12 with a first and second end, a plurality of channels 32, an anchoring distal plate 18 which articulates with the second end of the rod, a plurality of flexible wires 14, each having a proximal end and a distal end, a functional articulation point (the end of shaft 12) at the distal end of the wires, and a locking mechanism (column 5, lines 14-18) at each of a plurality of openings in the anchoring plates. A central opening for articulation with the central rod is situated at the epicenter of a plurality of openings in the anchoring plate 16 (see Fig. 2B). As to claims 54 and 55, note column 5, 10-11. Since the rod is slidable within the central opening, the diameter of the central opening is inherently larger than the diameter of the rod. As to claim 59, note column 5, lines 14-18. As to claim 1, Klingenstein shows an expandable surgical retractor comprising a central rod 12 with a first and second end, an end receptacle that articulates with the end of rod 12 with articulates with the second end of the rod, a plurality of anchoring plates 16, 18 slidably articulated with the central rod. The anchoring plates has a plurality of openings 22 wherein a plurality of flexible wires 14, each having a proximal end and a

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distal end, a functional articulation point (the end of shaft 12) at the distal end of the wires. The wires may be placed in the plurality of the openings. The retractor includes a locking mechanism (column 5, lines 14-18) at each of a plurality of openings in the anchoring plates. A central opening for articulation with the central rod is situated at the epicenter of a plurality of openings in the anchoring plate 16 (see Fig. 2B). Since the rod is slidable within the central opening, the diameter of the central opening is inherently larger than the diameter of the rod. Also, since the wires are slidable within the plurality of openings, the diameter of the opening is inherently larger than the diameter of the wires. As to claims 11, , note that figure 2B shows the rod to be solid. As to claims 13 and 63, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claims 64, 66, 68 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah et al (6,280,414). Shah shows an expandable surgical retractor comprising a handle 44 with an aperture 26, a plurality of openings 24 in the handle around the opening, and a plurality of flexible wires 10 in the openings. The wires enter one opening and exits through a separate opening. As to claims 68 and 69, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenstein (5,730,726). Klingenstein does not disclose instructions. However, the printed matter of the instructions is not functionally related to the retractor and therefore does not distinguish the invention from the prior art in terms of patentability. The claim differs from the prior art only in what the printed matter states. In order for this printed matter to impart patentability to the kit, there must be some functional relationship between the printed matter and some element of the kit. **What constitutes a functional relationship?** In *In re Miller*, 164 USPQ 46 (CCPA), the court found a functional relationship between the legend receptacle, the volumetric indicia thereon, and the legend indicating the ratio. In *In re Gulack*, 217 USPQ 410 (Fed. Cir.), the court found a functional relationship between the digits and the endless band since the band supported the digits in an endless sequence with each digit residing in a unique position with respect to every other digit in an endless loop. Therefore, in a situation, which has claims to kits of instruments or tools with instructions having nothing more than the bare recitation that the instructions are present, there is no functional relationship between the printed matter on the instructions and any other component of the kit. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was

made to provide the retractor with instructions for assembly and use. As to claim 31, the retractor is considered to be made of disposable material because it can be disposed of if desired. As to claim 33, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claims 12, 34-37, 39, 40, 44, 46-48 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenstein (5,730,726) in view of Starkweather (1,155,169). Klingenstein shows an expandable surgical retractor comprising a central rod 12 with a first and second end, a plurality of channels 32, an anchoring distal plate 18 which articulates with the second end of the rod, a plurality of flexible wires 14, each having a proximal end and a distal end, a functional articulation point (the end of shaft 12) at the distal end of the wires, and a locking mechanism (column 5, lines 14-18) at each of a plurality of openings in the anchoring plates. A central opening for articulation with the central rod is situated at the epicenter of a plurality of openings in the anchoring plate 16 (see Fig. 2B). Starkweather shows a retractor comprising a central rod 5 with a first end and a second end, an end receptacle 6, a plurality of anchoring plates 17 slidably articulated to the rod, wherein each of the plates contain a plurality of openings 16, and a plurality of flexible wires 18. It would have been obvious to one of ordinary skill in the art to provide the retractor of Klingenstein with a plurality of anchoring plates, as taught by Starkweather, in order to provide more support for the wires. As to claims 12, 47 and 62, Klingenstein does not disclose that the central rod is hollow. The rod of

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Starkweather is hollow so that an agent may be introduced through orifices 7. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the central rod of Klingenstein hollow, as shown by Starkweather, so that a therapeutic agent may be introduced into the body, if needed. As to claims 39 and 40, since the rod is slidable within the central opening, the diameter of the central opening is inherently larger than the diameter of the rod. Also, since the wires are slidable within the plurality of openings, the diameter of the opening is inherently larger than the diameter of the wires. As to claim 48, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In *re Hutchison*, 69 USPQ 138.

Claims 5, 25, 28, 53 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenstein (5,730,726) in view of Horzewski et al (5,201,756). The components of Klingenstein are not composed of a fiber optic material. Horzewski shows a radially-expandable tubular medical device wherein the tubular device is embedded with fiber optic bundles 40 and 41. The bundles enable visualization of the surgical site by delivering light to the site and sending an image back. It would have been obvious to one of ordinary skill in the art at the time the invention was made to compose one or more of the components of Klingenstein of fiber optic material, as taught by Horzewski, in order to enable visualization of the surgical site.

Claims 14-20, 22-26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenstein (5,730,726) in view of Starkweather (1,155,169) and



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Horzewski et al (5,201,756). Klingenstein shows an expandable surgical retractor comprising a central rod 12 with a first and second end, a plurality of channels 32, an anchoring distal plate 18 which articulates with the second end of the rod, a plurality of flexible wires 14, each having a proximal end and a distal end, a functional articulation point (the end of shaft 12) at the distal end of the wires, and a locking mechanism (column 5, lines 14-18) at each of a plurality of openings in the anchoring plates. A central opening for articulation with the central rod is situated at the epicenter of a plurality of openings in the anchoring plate 16 (see Fig. 2B). Starkweather shows a retractor comprising a central rod 5 with a first end and a second end, an end receptacle 6, a plurality of anchoring plates 17 slidably articulated to the rod, wherein each of the plates contain a plurality of openings 16, and a plurality of flexible wires 18. It would have been obvious to one of ordinary skill in the art to provide the retractor of Klingenstein with a plurality of anchoring plates, as taught by Starkweather, in order to provide more support for the wires. Also, the components of Klingenstein are not composed of a fiber optic material. Horzewski shows a radially-expandable tubular medical device wherein the tubular device is embedded with fiber optic bundles 40 and 41. The bundles enable visualization of the surgical site by delivering light to the site and sending an image back. It would have been obvious to one of ordinary skill in the art at the time the invention was made to compose one or more of the components of Klingenstein of fiber optic material, as taught by Horzewski, in order to enable visualization of the surgical site.

Claims 14-20, 22-26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenstein (5,730,726) in view of Volz et al (5,976,079).

Klingenstein does not disclose that the distal end of the wires are blunt and bulbous. Volz shows a lifting device formed of wire wherein the distal end 4 is blunt and bulbous to prevent injury to the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the wires of Klingenstein blunt and bulbous, as taught by Volz, in order to prevent injury to the tissue when the wires are being inserted within the body.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenstein (5,730,726) in view of Starkweather (1,155,169) and Horzewski et al (5,201,756), as applied to claim 14, and further in view of Volz et al (5,976,079).

Klingenstein does not disclose that the distal end of the wires are blunt and bulbous. Volz shows a lifting device formed of wire wherein the distal end 4 is blunt and bulbous to prevent injury to the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the wires of Klingenstein blunt and bulbous, as taught by Volz, in order to prevent injury to the tissue when the wires are being inserted within the body.

Claims 41 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenstein (5,730,726) in view of Starkweather (1,155,169) as applied to claim 34, and further in view of Horton (3,192,928). Neither Klingenstein or Starkweather teach that the articulation point is the meeting of at least two wires or that the meeting of the wires forms a cup shape. Horton shows a retractor formed of wires 38 that have a

functional articulation point 48 formed the meeting of to of the wires. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the wires of Klingenstein as shown by Horton, so that the device may be made of metal which flexible and strong.

Claims 56 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenstein (5,730,726) in view of Horton (3,192,928). Klingenstein does not teach that the articulation point is the meeting of at least two wires or that the meeting of the wires forms a cup shape. Horton shows a retractor formed of wires 38 that have a functional articulation point 48 formed the meeting of to of the wires. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the wires of Klingenstein as shown by Horton, so that the device may be made of metal which flexible and strong.

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (6,280,414) in view of Horton (3,192,928). The wires of Shah do not enter one opening and exit a separate opening. Horton shows a retractor device, and in Figure 4, the wires extend from one location on ring 36 and returns to a different location on the ring. This configuration allows the device to be made of metal which is flexible and strong. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the wires of Klingenstein as shown by Horton, so that the device may be made of metal which flexible and strong.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (6,280,414) in view of Williams (2203/0095781). The handle of Shah does not

include a light source. Williams shows a variety of surgical instruments with light sources. In particular, Figures 13 and 14 show a light source 952 located in the handle 970. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the handle of Shah with a light source, as taught by Williams, in order to provide a better view of the surgical site.

### ***Allowable Subject Matter***

Claims 29, 30, 42 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 57 and 58 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The channels, as set forth in claim 49, is not included in the specification.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the locking mechanism, the flexible wires having a blunt and bulbous distal end, the articulation mechanism (see claims 42 and 43), and a plurality of channels around the central rod,

must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.


Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cary E. O'Connor whose telephone number is 571-272-4714. The examiner can normally be reached on M-Th 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Cary E. O'Connor  
Primary Examiner  
Art Unit 3732

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